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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/719,415

11/21/2003

Dusan Pavcnik

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COOK GROUP PATENT OFFICE

P.O. BOX 2269

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EXAMINER

PRONE, CHRISTOPHER D

ART UNIT

PAPER NUMBER

3738

MAIL DATE

DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/719,415	<b>Applicant(s)</b> PAVCNIK ET AL.	
	<b>Examiner</b> CHRISTOPHER D. PRONE	<b>Art Unit</b> 3738	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 25 February 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1 and 3-22 is/are pending in the application.
- 4a) Of the above claim(s) 3, 13, 15 and 19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 4-12, 14, 16-18 and 20-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 6, 9-11, 14, 17, 18, and 20-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over United States Patent 5,865,723 Love in view of United States Patent 5,891,193 Robinson et al.

Love discloses the invention substantially as claimed comprising expandable first inner stent 16, expandable second outer stent 14, and a tissue graft layer 12 comprising an extra cellular matrix material collagen disposed on the first stent and under the second. Love also discloses that the stent may comprise a plurality of circumferential segments and a plurality of tie bars shown in figure 9. In regards to claims 17, figure 2 of Love shows that the outside diameter of the first stent is greater than the inside diameter of the second stent. In regards to claim 18 Love further discloses that the first and second stents have equivalent inside and outside diameters (7:25-37).

However, Love does not disclose that the distal and proximal most portions of the first stent are at least coincident with or extend beyond the distal and proximal most ends of the graft.

Robinson teaches the use of a tubular implant comprising a tissue graft 20 and an inner expandable stent member having anchors that extend beyond the grafts distal

and proximal ends in the same field of endeavor for the purpose of securely anchoring the distal and proximal ends of the implant to the operation site.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the implant of Love have stent anchor extensions that extend beyond the graft ends as taught by Robinson in order to better anchor the implant to the vessel.

Claims 4, 5, 7, and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Love in view of Robinson and further in view of United States Patent 6,358,284 B1 Fearnot et al.

The combination of Love in view of Robinson discloses the invention substantially as claimed being disclosed above. However, the combination does not disclose that the tissue graft comprises multiple layers of submucosa.

Fearnot teaches the use of tubular grafts comprising layers of submucosa sheets in the same field of endeavor for the purpose of providing enhanced repair of damaged or diseased host tissues.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the submucosa tissue graft layers as taught by Fearnot with the stent graft of Love as modified by Robinson in order to provide enhanced repair of damaged or diseased host tissues.

Claims 1, 12, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over United States Patent 5,628,788 Pinchuk in view of United States Patent 6,358,284 B1 Fearnot et al.

Pinchuk discloses the invention substantially as claimed being a double-layered stent graft wherein the inner stent is smaller than the outer stent and the ends of each layer are at least coincident as seen in figures 3-9. However, Pinchuk does not disclose that the graft comprises multiple layers of tissues.

Fearnot teaches the use of tubular grafts comprising layers of submucosa tissue sheets in the same field of endeavor for the purpose of providing enhanced repair of damaged or diseased host tissues.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the submucosa tissue graft layers as taught by Fearnot with the double layered stent graft of Pinchuk in order to provide enhanced repair of diseased host tissues and better anchoring and expansion.

### ***Response to Arguments***

Applicant's arguments filed 2/25/08 have been fully considered but they are not persuasive.

The applicant argues that neither Love nor Robinson disclose the same motivation for combining as that of the current application. This does not overcome the rejection because the motivations do not need to be identical. As long as there is an obvious motivation and the claimed structure is met the art will read on the claims. The

applicant then argues that Love teaches away from this combination. This is not convincing because Love fails to actually teach against this combination. Love provides support that in one embodiment the graft may extend beyond the frame, but never says that this is necessary or that the frame extending to the end of the graft or beyond the graft is a bad thing. The office action discloses a clear motivation for the combination above, which the applicant has failed to provide any factual evidence as why it would not work or how it ruin the device.

Applicant argues that the combination further including Fearnot does not read on the claims for the same reasons as above. As described above the arguments are not convincing therefore this combination remains proper.

Applicant argues that Pinchuk fails to show ends of the stent and graft that are at least coincident. However it is clear from the figures of Pinchuk, emphasis on figures 5 and 6 that both the proximal and distal ends are at least coincident. The applicant further argues that the examiner was convinced that Pinchuk fails to teach this claim requirement. However upon further review the rejection was made because figures 5 and 6 of Pinchuk clearly show the entire device and it is clear from these figures that all of the ends are at least coincident.

The applicant argues that none of the art of record appreciates the advantages of coincident ends. The art may or may not have come to the exact same motivation for having coincident ends, but it is definitely very old and well known to have stent grafts have coincident ends for a variety of other reasons.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D. Prone whose telephone number is (571) 272-6085. The examiner can normally be reached on Monday through Fri 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Christopher D Prone  
Examiner  
Art Unit 3738

/Christopher D Prone/

/DAVID J ISABELLA/

Supervisory Patent Examiner, Art Unit 3774